K061666

AUG 24 2006

10.0 Premarket Notification Special 510(k) Summary

In accordance with the Safe Medical Devices Act of 1990 and 21 CFR 807.92, a Premarket Notification 510(k) Summary for the F-600 system Premarket Notification is provided below

10.1 Submitter Information

Company Name and Address:

Mauna Kea Technologies
9, rue d'Enghien
75010 Paris
France

Contact Name:

Fouad Tarabah, PharmD.
Director of Quality and Regulatory Affairs
Mauna Kea Technologies
Telephone: +33 1 70 08 09 61
Fax: +33 1 48 24 12 18
e-mail: fouad@maunakeatech.com

Date Prepared: May 2006

10.2 Name of Device

Proprietary Name: Cellvizio® (-GI, -LUNG) with Confocal Miniprobe™ (Coloflex, Gastroflex, Alveoflex)

Classification Name: Endoscope and/or Accessories

10.3 Predicate Device(s) Information

Pentax Confocal Laser System, K042740

Pentax EC-3870CILK Confocal Video Colonoscope, K042741

superDimension Bronchus, K042438

10.4 Device Description

The Cellvizio® (-GI, -LUNG) with Confocal Miniprobe™ (Coloflex, Gastroflex, Alveoflex) is a confocal microscope with a fiber optic probe which allows *in vivo* visual inspection of tissues with a microscopic resolution during an endoscopic procedure. The F-600 system has been designed to allow real-

K061666

time observations of tissues. The device is based on a common laser scanning technology adapted for imaging through a bundle of optical fibers and is thus composed of several elements: a Laser Scanning Unit, proprietary software running on a remote computer, a flat panel display and Miniaturized Fiber Optic Probes. The F-600 system can be used with any legally marketed endoscope with a working channel of 2.8 mm or greater.

10.5 Intended Use

The Cellvizio® (-GI, -LUNG) with Confocal Miniprobe™ (Coloflex, Gastroflex, Alveoflex) is a confocal laser system that is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical tract, i.e., gastrointestinal or respiratory, accessed by the endoscope.

10.6 Comparison to Predicate Device(s)

The comparison to the predicate devices was based on a review of the F-400 system information included in the company's 510(k) Premarket Notification K051585 and information concerning the predicate devices that was available in the public domain. The F-400 system is the Mauna Kea Technologie's legally marketed device (K051585) which serves as the unmodified device for the Cellvizio® (-GI, -LUNG) with Confocal Miniprobe™ (Coloflex, Gastroflex, Alveoflex) special 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2006

Mauna Kea Technologies
% Fouad Tarabah
Director of Quality and Regulatory
Affairs
9, Rue D'Enghien
Paris, France 75010

Re: K061666
Trade/Device Name: Cellvizio® (-GI, -LUNG) with Confocal Miniprobe™ (Coloflex, Gastroflex, Alveoflex)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: June 20, 2006
Received: June 25, 2006

Dear Fouad Tarabah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product

radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ODE Indications Statement

Special 510(k) Number (if known): K061666

Device Name: Cellvizio® (-GI, -LUNG) with Confocal Miniprobe™ (Coloflex, Gastroflex, Alveoflex)

Indications for Use:

The Cellvizio® (-GI, -LUNG) with Confocal Miniprobe™ (Coloflex, Gastroflex, Alveoflex) is a confocal laser imaging system with fiber optic probes that is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical tract, i.e., gastrointestinal or pulmonary, accessed by the endoscope.

Prescription Use: X AND/OR Over-the-Counter Use:

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruno for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061666